PSJ15 Exh 81

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Controlled Substance Quota and Suspicious Order Monitoring Overview

Presentation for
Supply Chain Council
02/20/12

Discussion Topics

Controlled Substance Market Controls

Quota Overview

DEA Office of Diversion Control Responsibilities

Suspicious Order Monitoring Update

DEA Enforcement Action

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"To rule is easy,
to govern is difficult"

Johann W. von Goethe

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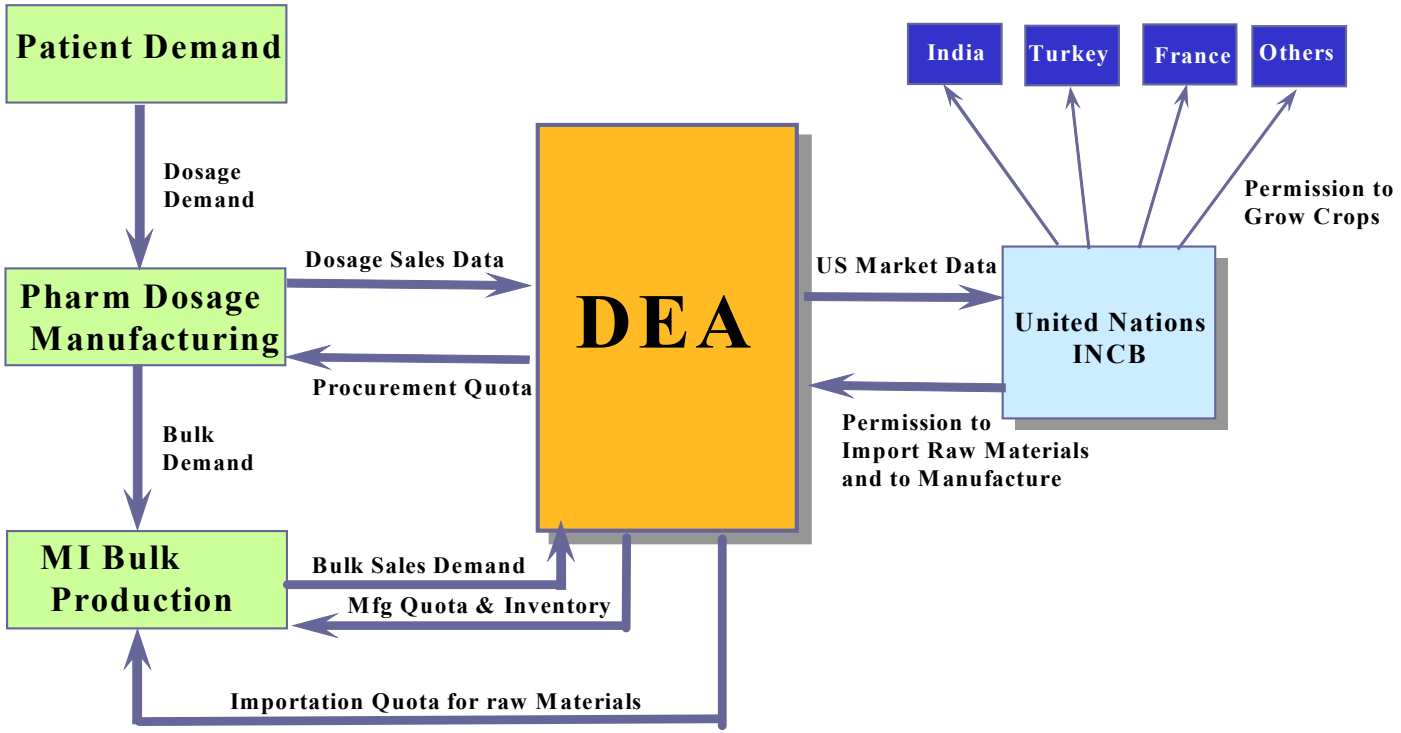
Narcotics Market Controls



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Global Narcotics Market Controls

International Narcotics Control Board INCB

Quasi-judicial entity of the United Nations

Administer International Estimate (quota) system

Measure and monitor consumption
- 6 countries representing 20% of the world's population accounted for 95% of all morphine consumption in 2005

Administers the 80/20 rule to force narcotic raw material purchases to "traditional" sources

186 Countries are treaty signatories
8 Countries are not party to the 1961 Convention

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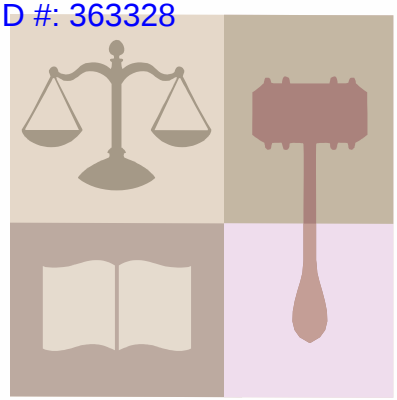
Quota Overview



U.S. Aggregate

Established by DEA annually by January 1
One “mid-year” revision to U.S. Aggregate
U.S. Aggregate represents the upper limit of national production
Quotas are applicable to CI and CII controlled substances
Quotas are drug code (base class molecule) specific

Manufacturing Quotas

Site specific
Bulk manufacturing synthesis (codeine to hydrocodone)
Extraction from plant material (opium, poppy straw, coca leaf)

Procurement Quotas

Site specific
Acquisition of controlled substances for:
- Product development
- Dosage form manufacture
- Repackaging or relabeling

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Quota Calendar

Example below assumes 2012 calendar year quota cycle

April 1, 2011	Submit 2012 Procurement Quota requests for Hobart (sku specific), Webster for next calendar year (research project specific), and Building 50, St. Louis narcotic raw materials
May 1, 2011	Submit 2012 Bulk Manufacturing quota requests for API production in St. Louis for next calendar year DEA requires a quota quantity request with no forecast information for this submission
October/November, 2011	DEA publishes the Proposed Initial 2012 U.S. Aggregate for next calendar year 30 day Federal Register comment period Increases to previously submitted bulk manufacturing requests require customer specific forecasts During this time, we also revisit previously submitted procurement quota data and forward increase requests as needed
January 1, 2012 or sooner	DEA publishes the Initial 2012 U.S. Aggregate for the new calendar year DEA sends individual manufacturing quota grant letters DEA sends procurement quota grant letters
Mid-Year	DEA publishes the Proposed Revised 2012 U.S. Aggregate for the current calendar year **note**: the Mid-Year Proposed Revised Aggregate timing varies significantly, see next slide 30 day Federal Register comment period Increases to previously submitted bulk manufacturing requests require YTD Actual Sales + Future Forecasted Sales + justification statements
Periodically	DEA accepts requests for increases to either procurement quotas or manufacturing quotas at any time YTD Actual Sales + Future Forecasted Sales + justification statements

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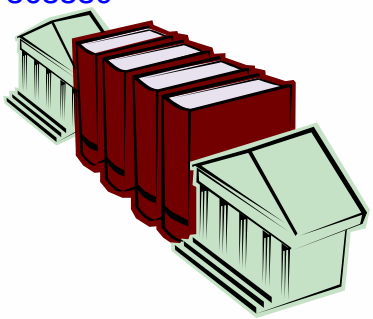
Revised Aggregate Historical Timing



	Proposed Revised Aggregate Fed Register Publication	Length of Comment Period	End Date of Fed Register Comment Period	Final Revised Aggregate Fed Register Publication	Elapsed Time End of Proposed Revised Aggregate Comment Period to Publication of Final Aggregate
1999	08/20/99	30 days	09/20/99	10/19/99	29 days
2000	07/19/00	30 days	08/18/00	09/25/00	38 days
2001	08/06/01	30 days	09/05/01	10/15/01	40 days
2002	07/23/02	30 days	08/22/02	09/20/02	29 days
2003	08/06/03	21 days	08/27/03	09/30/03	34 days
2004	09/09/04	21 days	09/30/04	11/16/04	47 days
2005	08/05/05	21 days	08/26/05	11/09/05	75 days
2006	07/06/06	21 days	07/26/06	10/19/06	85 days
2007	05/03/07	21 days	05/24/07	08/27/07	95 days
2008	07/01/08	30 days	07/31/08	11/12/08	104 days
2009	07/23/09	30 days	08/24/09	10/21/09	58 days
2010	06/23/10	30 days	07/23/10	09/14/10	53 days
2011	09/14/11	30 days	10/14/11	12/12/11	58 days

2011 Proposed Revised Aggregate publication received later in the year than the previous 12 years

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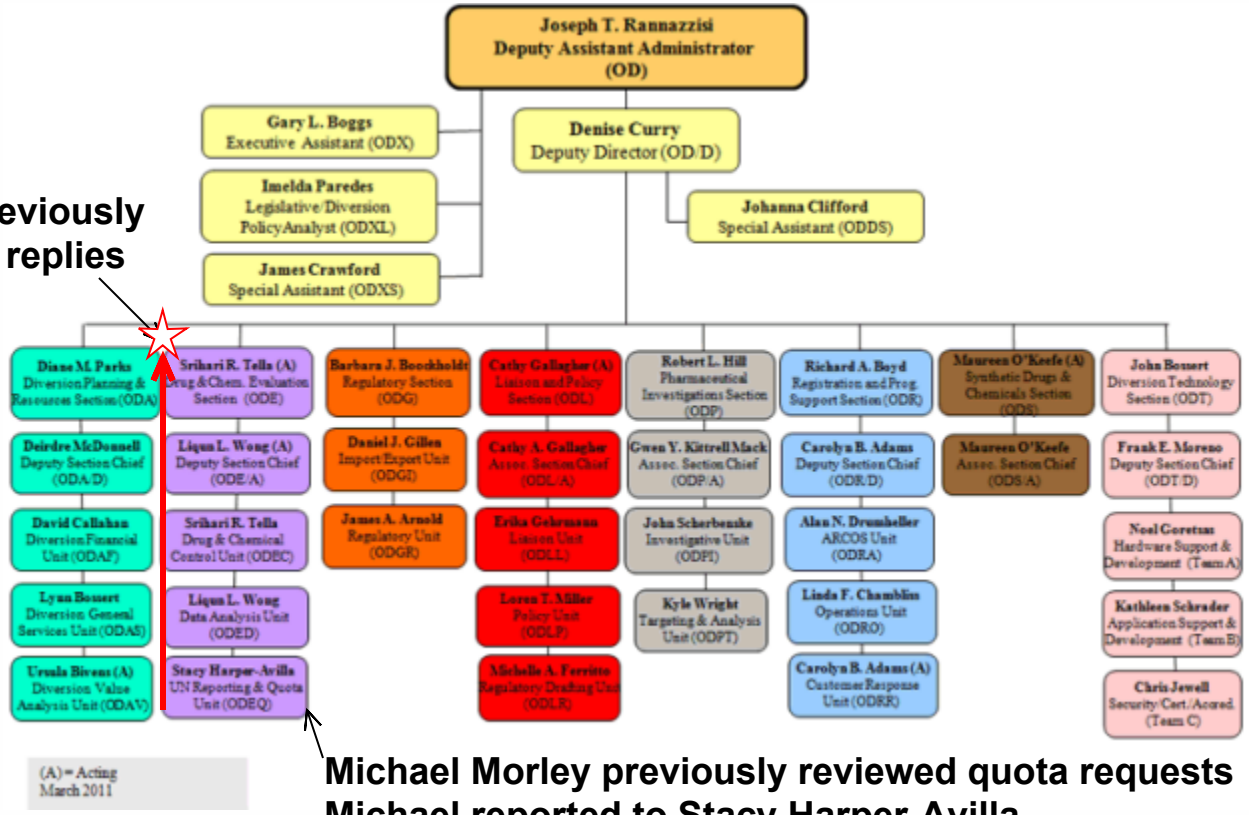
DEA Office of Diversion Control
Previous Quota Authorization Process

ODE Chief previously signed quota replies



Michael Morley previously reviewed quota requests
Michael reported to Stacy Harper-Avilla

Code of Federal Regulations, Title 21
INDIVIDUAL MANUFACTURING QUOTAS
Section 1303.21 Individual manufacturing quotas

(a) The **Administrator** shall, on or before July 1 of each year, fix for and issue to each person who is registered to manufacture a basic class of controlled substance listed in Schedule I or II, and who applies for a manufacturing quota, an individual manufacturing quota authorizing that person to manufacture during the next calendar year a quantity of that basic class. Any manufacturing quota fixed and issued by the **Administrator** shall be subject to his authority to reduce or limit it at a later date pursuant to Sec. 1303.26 and to his authority to revoke or suspend it at any time pursuant to Secs. 1301.36 of this chapter.

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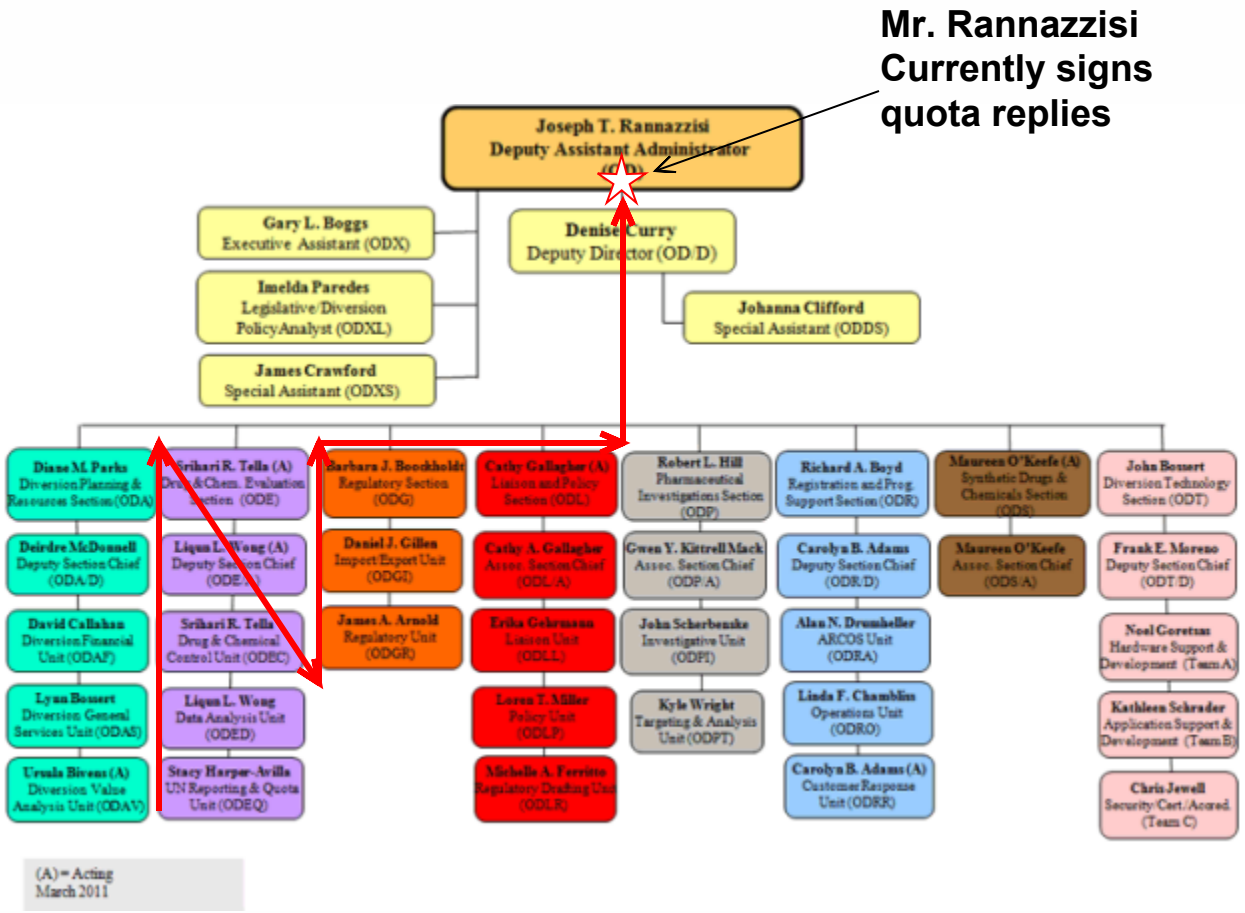
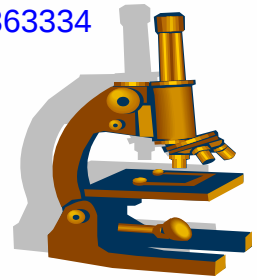
DEA Office of Diversion Control
Current Quota Authorization



Revised Quota Review Process
Per DEA 06/11



Quota group receives the letter and enters request into database

Quota group processes (request is evaluated against aggregate and our sales information is confirmed); recommends full, partial, or zero grant

External Review 1 - DEA Registration Unit
Confirms company is in good standing (license is currently renewed, no revocation action)

External Review 2 - DEA Investigative Section
Verifies no current investigations involving company

External Review 3 - Targeting & Analysis (Suspicious Order Monitoring Group)
Makes sure the material is not being used to complete suspicious orders

Quota group Section Chief reviews grant

Front office (Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration) reviews and signs the grant letter

Bolded items in red are new reviews

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Existing SOM Program (pre 06/10)

- Customer completes checklist prior to establishing new account and once annually thereafter
- Credit performs Dun & Bradstreet and other information checks (Associated Pharmacies)
- CDIG and CSRs follow existing procedure on verification of customer DEA registration, quota, DEA 222 Form
- Peculiar Order report flags direct orders of unusual size, frequency, incremental increases, purchase of a new molecule or business from a new customer
- Any Peculiar Order issues that are not resolved by internal investigation are referred to the Controlled Substance Compliance Group Security Director and DEA Compliance Manager for further investigation
- Security Director and DEA Compliance Manager consult with Commercial Group Business Manager regarding ship or no ship decision based on findings of their investigation
- Security Director and DEA Compliance Manager report orders that have been elevated from Peculiar to Suspicious to DEA

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"If everything seems to be going well,
you have obviously overlooked something"

Murphy's Laws

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DEA St. Louis Conversation 07/20/10

Mallinckrodt was named as supplier of Harvard Drug Distributor at a DEA training session in Washington DC

Pain Clinic undercover operations reveal a “cattle call” scenario

Mallinckrodt is viewed as the kingpin within the drug cartel

DEA is implementing a “new direction” initiative aimed at manufacturers of Oxycodone

DEA expectation has evolved to require that manufacturers know their customers’ customers

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Mallinckrodt Suspicious Order Monitoring (SOM) Team Composition

Pharma Executive Leadership Team

Pharma President and select staff

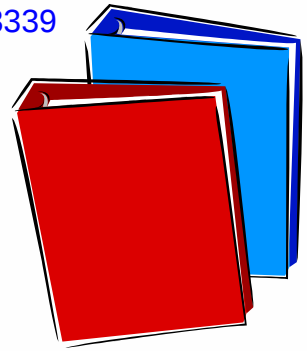
SOM Leadership Team

Controlled Substance Compliance
Security
Legal

SOM Steering Committee

Controlled Substance Compliance
Security
Legal
Commercial
Customer Service
Finance
Medical Affairs/REMs

Subcommittees



SOM Program Enhancements Achieved

Monthly review of Chargeback Reports

- Data analysis reveals
  - % of Oxycodone purchased per Distributor
  - % of Distributor Oxycodone sold to Florida
  - Pharmacies that purchase from multiple Distributors

Distributor Audit Program Implemented

Met with DEA Albany and DEA St. Louis to discuss Chargeback Report observations

Conducted on-site SOM Audit of Keysource, Masters, Cedardale

Informed Distributors of audit findings 02/11

All communication to Distributors has been pre-reviewed by Commercial

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LEAVE PRESCRIPTIONS HERE
NO INSURANCE FOR ANY Roxicodone
FREE SODA OR WATER WHILE YOU WAIT FOR YOUR RX'S.
NO CELL PHONE USE IN PHARMACY
All new patients must have their MRI report or else have your doctor fax us a copy of the report. 561-588-8562
WE DO NOT ACCEPT ANY INSURANCE ON : OXYCODONE PRODUCTS BY MALLINCKRODT OR ACTAVIS. OXYCONTIN. OXYCODONE ORAL SOLUTION. OXYCODONE ER OR LA PRODUCTS.
DURACELL
QUIET PLEASE
CarPlanes
Murine TEARS
Systane ULTRA

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"There are lies, there are damned lies,
and there are statistics."

Mark Twain

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Suspicious Order Monitoring Update

DEA Meeting in Washington DC 08/23/11

Meeting at Mallinckrodt request

DEA confirmed they are under tremendous pressure from Congress and White House to address the Florida oxycodone problem

DEA showed Mallinckrodt statistics demonstrating that it appears a disproportionate amount, compared to national averages, of our Oxy 15 and 30 mg are ending up in Florida pharmacies

Mallinckrodt Action Taken

We have met in person with the “Big 4” and conducted phone meetings with smaller wholesaler/distributors

Of 160 pharmacies reviewed, 61 are blocked

37 of the blocked pharmacies are in Florida

5 very large volume Nevada pharmacies have been blocked

Top 3 pharmacies in U.S. have been blocked

Pharmacies represent 8% of distributor sales of Oxycodone 30 mg nationwide (1/11-8/11)

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By the Numbers

There are currently 1,363,883 DEA registrants
795 Distributor registrants
528 Manufacturing registrants

"DEA must rely on the States and individual registrants to monitor"

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Covidien has 1,300+ controlled substance customer accounts

1,100+ Generics & Specialty Brands
200+ Active Pharmaceutical Ingredients

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"Don't taunt the alligator
until after you have crossed
the creek"

Dan Rather

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DEA Distributor Initiative, 2008

Amerisource Bergen

Orlando, FL Distribution Licenses suspended for four months

Cardinal

DEA license suspended at three distribution centers for ten months
Cardinal pays $34 million due to enforcement actions

McKesson

McKesson Corporation Agrees to Pay More than $13 million to settle claims that it failed to report suspicious sales of prescription medications

DEA suspends licenses of distributors for not maintaining effective controls against diversion of controlled substances

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CVS Fines

CVS Caremark's Latest Legal Headaches? A Record $77.6 Million Settlement with DEA
Published October 15, 2010

The already extensive list of government entities scrutinizing CVS Caremark's behavior just got longer. DEA joins the alphabet soup with a record $77.6 million settlement, which includes a $75 million fine (the largest ever under the Controlled Substances Act) and the forfeiture of $2.6 million in profits from illegal sales. Meanwhile, a California court upheld a $42,000 fine against Caremark for acting in "bad faith" in a whistleblower lawsuit.

In a statement, the U.S. Drug Enforcement Administration said the company, *"admitted that it unlawfully sold pseudoephedrine [PSE] to criminals who made methamphetamine. As part of the agreement with federal prosecutors, CVS has agreed to pay $75 million in civil penalties and to forfeit the $2.6 million in profits the company earned as a result of the illegal conduct."*

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Cardinal Distribution

DEA Action 02/03/12

The Feds Step In –

Cardinal announced today that the DEA has immediately suspended the license of its Lakeland, FL distribution center to distribute controlled medicines.

The DEA contends alleges that four of Cardinal Health's retail pharmacy customers dispensed controlled substances based on prescriptions that were issued for other than a legitimate medical purpose.

The DEA also alleges that Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels.

Cardinal is seeking a restraining order on the DEA's action to prevent disruption to those pharmacies served by that facility.

Cardinal Press Release
While early in this process, we believe this seems to be an over reach on the DEA's part on the responsibilities that Cardinal should have for supervising the dispensing patterns of independent pharmacists.

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Listed in category: Crafts > Multi-Purpose Craft Supplies > Display & Storage

Item: 28058

Pharmacy 54 Empty Mallinckrodt Oxycodone Pill Bottles

blask_fl (287 ★)

Item condition: **Used**

Time left: 3d 05h (Oct 31, 2010 17:05:17 PDT)

Bid history: 0 bids

Starting bid: **US $0.99**

You are bidding on 54 cleaned used empty pill bottles with 54 child safety caps/lids.

Dimensions:

2 and 6/16" tall with cap, 2 and 3/16" tall w/o cap.
1 and 7/16" diameter, 13/16" mouth.

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"People who work together will win,
whether it be against complex football defenses,
or the problems of modern society."

Vince Lombardi

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Questions and comments

Thank you

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